

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION  
CIVIL NO. 3:17-CV-37

UNITED STATES OF AMERICA *ex rel.*  
TARYN HARTNETT, and DANA  
SHOCHED,

Plaintiff,

v.

PHYSICIANS CHOICE LABORATORY  
SERVICES, DOUGLAS SMITH, PHILIP  
MCHUGH AND MANOJ KUMAR,

Defendants.

**MEMORANDUM IN SUPPORT OF THE  
UNITED STATES' MOTION FOR  
SUMMARY JUDGMENT AS TO  
DEFENDANT DOUGLAS SMITH**

Defendant Douglas Smith directed and participated in a kickback scheme to induce the referral of urine drug testing (“UDT”) samples, including those from Medicare beneficiaries, to Physicians Choice Laboratory Services (“PCLS”), a toxicology lab in which he had a significant ownership interest and from which he personally received roughly \$47 million in distributions over the course of its operations. Specifically, Smith paid \$300,000 to his business associate, James “Jim” Lord, to fund Lord’s purchase of a medical practice in Knoxville, Tennessee, in order to the referral of UDTs to PCLS. Not only did Smith pay this remuneration with the intent to induce the referral of UDT samples to PCLS, he was successful in doing so: witness testimony and claims data show a tight temporal nexus between the payment of the kickback and the referral of samples. PCLS billed Medicare for these referrals, and because claims tainted by kickbacks are *per se* false claims, the United States seeks entry of judgment against Smith, finding him liable under the False Claims Act (Counts I and II), and awarding treble damages and assessing civil penalties as compensation for the loss to the Medicare program.

## **SUMMARY JUDGMENT STANDARD**

Summary judgment is “properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to secure the just, speedy, and inexpensive determination of every action.” *Celotex Corp.*, 477 U.S. 317, 327 (1986). It should be rendered if materials in the record, including but not limited to, depositions, documents, electronically stored information, affidavits or declarations, interrogatory answers, or other materials. Fed. R. Civ. P. 56(c)(1)(A). The moving party bears the burden of demonstrating that there is no dispute as to any material fact in the case. *Celotex*, 477 U.S. at 323. The Supreme Court has clarified that this does not mean that *any* factual dispute will defeat the motion: “[b]y its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A dispute about a material fact is genuine only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Id.* at 248.

Additionally, the United States requests that its first set of Admissions served on Smith be admitted based on Smith’s failure to respond within the period of time required by the Federal Rules of Civil Procedure or thereafter. “Unanswered requests for admissions are considered admitted as a matter of law,” Fed R. Civ. P. 36(a); *Batson v. Porter*, 154 F.2d 566, 568 (4th Cir. 1946), and may properly serve as a basis for summary judgment. *Adventis, Inc. v. Consol. Prop. Holdings, Inc.*, 124 F. App’x 169, 173 (4th Cir. 2005). “[O]nce a matter that is properly subject of an admission under Rule 36(b) has been admitted during discovery, the district court is not free to disregard that admission.” (*Id.*) (citations omitted); see *La Michoacana Nat., LLC v. Maestre*, 2019 WL 2403106, at \*1 (W.D.N.C. June 6, 2019) (*vacated by La Michoacana Nat., LLC v. Maestre*,

2020 WL 1233652 (W.D.N.C. Mar. 12, 2020) (where order granting summary judgment was grounded entirely on counsel’s false representation that defendant never responded to RFAs)); *Acosta v. Del Sol P’ship 2, Inc.*, 2018 WL 907410, at \*1 (E.D.N.C. Feb. 15, 2018). This is an appropriate use of admissions, especially when sufficient notice of the effect of failure to respond was provided to the non-movant, and the movant does not rely solely on the admissions to support summary judgment. *See United States v. Renfrow*, 612 F. Supp. 2d 677, 681-83 (E.D.N.C. 2009); *see also United States v. Garcia-Soto*, 2011 WL 486186, at \*1 (E.D.N.C. Feb. 7, 2011); *USRP (Gant 1), LLC v. Langston*, 2006 WL 4681143, \*2 (E.D.N.C. March 13, 2006) (collecting cases); *United States v. 2204 Barbara Lane*, 960 F.2d 126 11th Cir. 1992) (applying principle to *pro se* litigant); *c.f. Jones v. Jack Henry & Associates, Inc.*, 2007 WL 4226083, at \*2 (W.D.N.C. Nov. 30, 2007) (declining to deem unanswered admissions where *pro se* litigant never advised that a failure to respond would result in material matters pertaining to this lawsuit being conclusively established against him).

### **LEGAL FRAMEWORK OF THE FCA AND AKS**

The Anti-Kickback Statute (“AKS”) specifically forbids any person or entity from knowingly and willfully offering, paying, soliciting, or receiving remuneration to influence the referral of items or services reimbursable by a federal healthcare program. 42 U.S.C. § 1320a–7b(b). The AKS “seeks to ensure that referrals will be based on sound medical judgment and that health care professionals will compete for business based on quality and convenience, instead of paying for referrals.” OIG Advisory Op., No. 12-06, at 7 (May 25, 2012). As courts have long recognized, “[t]he potential for increased costs to the Medicare-Medicaid system and misapplication of federal funds is plain . . . [these] are among the evils Congress sought to prevent

by enacting the kickback statutes.” *U.S. v. Hancock*, 604 F.2d 999, 1001-02 (7th Cir. 1979), *cert. denied*, 444 U.S. 991 (1979).

A violation of the False Claims Act, 31 U.S.C. §§ 3729-3733, occurs when a person “knowingly presents, or *causes* to be presented, a false or fraudulent claim for payment or approval” by the United States, 31 U.S.C. § 3729(a)(1)(A) (emphasis added), or “knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim...” *Id.* at §3729(a)(1)(B). “An AKS violation resulting in a federal health care payment automatically constitutes a false claim under FCA.” *U.S. ex rel. Hartnett v. Physicians Choice Laboratory Services, LLC*, 2020 WL 571322, at \*3 (W.D.N.C. Feb. 5, 2020) (Bell, J.) (citations omitted); *see also U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498 (D.S.C. 2016) (collecting cases).

### **BACKGROUND FACTS**

Defendant Smith was one of the original owners of PCLS (Ex. 1: Deposition of Joseph Wiegel (“J.W.”) 42:5-14; Ex. 2: United States of America’s First Request for Admissions to Defendant Douglas Smith at ¶1).<sup>1</sup> James “Jim” Lord was in the business of managing medical practices through his management company, Optimal Medical Management of Tennessee, LLC d/b/a Optimed (Ex. 3: Deposition of James Lord (“J.L.”) 13:10-24, 27:22-25; Ex. 2 at ¶9). Lord and Smith became acquainted in Charlotte, when a physician Lord was working for at the time suggested he learn more about MedEx, a software program developed by Smith (J.L. 18:6-19). Lord eventually went into business with Smith, and invested sweat equity in a joint venture related to the development of MedEx called American Rx (J.L. 18:25-19:16, 20:14-19, 21:8-21).

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<sup>1</sup> *See also* the United States’ Memorandum of Law in Support of its Motion for Partial Summary Judgment as to Defendant Philip McHugh, which is incorporated in its entirety as if fully set forth herein.

Southeast Spine and Pain Associates (“SSPA”) f/k/a Advanced Pain Therapeutics of Knoxville TN, LLC (“APT”) was a pain clinic in Knoxville, Tennessee, that at times referred patient samples to PCLS for UDTs (J.L. 44:10-19, 46:7-10; Ex. 2 at ¶3). In 2010, PCLS aggressively pursued APT as a customer, and APT became one of Physicians Choice Laboratory Services’ highest-volume referral sources and one of its biggest customers (Ex. 4: Deposition of John Grove 61:17-62:15; Ex. 2 at ¶5). At that time, APT was owned by Dr. Allen Foster and his wife, Sonia Foster (Ex. 2 at ¶4). Dr. Allen Foster, however, was incarcerated in or around 2011, and his wife continued to operate APT until its sale (J.L. 15:10-18; Ex. 2 at ¶6).

In July of 2012, Sonia Foster contacted Lord in an effort to sell him the practice (J.L. 15:22-16:4). At the time, Lord discussed the business opportunity with Smith (J.L. 25:4-7). Lord testified that he suggested to Smith that APT could be used as a “testing site” for their American Rx venture (J.L. 25:4-14). Specifically, they could “test” how effective utilizing multiple medical management techniques, including the American Rx “pharmacy” model and PCLS’ UDTs, would be to address the opioid crisis (J.L. 26:11-15).

Smith ultimately financed Optimed’s purchase of APT in 2012 (J.L. 56:21-25; Ex. 2 at ¶10). As part of the transaction, on August 13, 2012, Lord caused Portia S. Hutchinson to enter into a Membership Interest Purchase Agreement with Sonia Foster and APT, whereby Hutchinson purchased APT for the total price of \$834,892, due in certain installments (J.L. 28:12-25; Ex. 5: Membership Interest Purchase Agreement). At the time, Hutchinson was employed by Optimed as a nurse practitioner, and the sale was structured in this way to circumvent a Tennessee state law that prohibited non-physicians from owning pain management practices (J.L. 28:12-25, 29:7-19, 30:7-25). Lord explained that “it was never intended that Portia would have any financial liability for that purchase. It was always intended that it would be my company that would bear that

financial burden” (J.L. 34:10-14). To that end, Optimed signed a Guaranty Agreement for the benefit of Sonia Foster to guarantee the Promissory Note executed by Hutchinson (J.L. 34:21-35:4; Ex. 6: Promissory Note; Ex. 7: Guaranty Agreement).

Lord could not recall the exact figure, but believed Smith funded between \$200,000 and \$250,000 of the initial payments due to Sonia Foster (J.L. 29:20-30:6). Records reflect that to finance the purchase of APT, on August 27, 2012, Smith first caused his company Smith & Sons Ent, LLC, a Florida limited liability company, to pay \$50,000 to Optimed by check (J.L. 17:21-25; 38:1-10; Ex. 2 at ¶¶ 14, 15, 16, 18, 19 and p. 24). Then, on September 10, 2012, Smith caused Smith & Sons Ent, LLC to wire a payment of \$250,000 to Optimed (J.L. 40:1-11, 40:19-41:11; Ex. 2 at ¶¶ 17, 20 and p. 19).<sup>2</sup> Lord testified that Optimed then paid Sonia Foster (J.L. 41:12-43:3). He stated he thought he paid the initial \$250,000 to Sonia Foster, and could have kept the additional \$50,000 from Smith (J.L. 56:16-20).

After the sale, Lord renamed the practice to SSPA (J.L. 14:12-24; Ex. 2 at ¶13). Lord caused the practice to enter into a management agreement with Optimed, whereby Optimed performed certain services for SSPA, including financial, insurance, 401k and tax management, personnel management, IT, and “general troubleshooting” (J.L. 30:16-17, 49:17-15). Lord hired the practice’s first Medical Director (J.L. 35:10-20), and later, a practice manager (J.L. 49:1-10).

SSPA used PCLS for confirmation testing in the two years following the purchase by Smith and Optimed (J.L. 46:9-10). SSPA’s PCLS sales representative was Shaun Thompson, who was the developer of MedEx and the business partner of Lord and Smith in the American Rx venture (J.L. 20:13-21:7, 46:24-47:7). In July of 2014, SSPA stopped sending patient urine samples to

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<sup>2</sup> In September of 2012, Smith also bought Lord a \$36,000 BMW, because, according to Lord, Smith “hated my car” (which at the time, was a 2000 Cadillac Eldorado) (J.L. 60:2-17).

PCLS because Smith and Lord had a falling out (Ex. 2 at ¶25), or, according to Lord, because SSPA decided to bring confirmation testing in-house (J.L. 46:7-12). Lord admitted, however, that at some point in late 2012 or early 2013, his relationship with Smith “went South,” and they eventually divided up their business ventures and stopped working together (J.L. 55:13-18, 61:3-16). As part of the split, Lord retained SSPA (J.L. 56:2-7). Following the split, Optimed did not pay Smith back for any portion of the \$250,000 or \$300,000 he put towards the purchase of the practice (J.L. 56:9-15).

On June 20, 2019 the United States filed its Complaint in Intervention, alleging, among other things, the above-described kickback scheme (Dkt. 38). Smith was served with the Complaint on July 26, 2019, and his deadline to file an answer ran on August 16, 2019 (Dkt. 51). The United States moved for entry of default on November 15, 2019, noting Smith’s failure to appear, plead, or otherwise defend in the action (Dkt. 91). Smith filed his “answer” on November 19, 2019, and, instead of responding to the specific allegations of the Complaint, stated only that he “den[ied] all charges, allegations, and wrong-doing,” and requested a jury trial (Dkt. 92). The Court subsequently denied the United States’ Motion for Entry of Default by text-only order on December 18, 2019.

On October 16, 2020, the United States served its First Request for Admissions on Smith (the “Request”) (Ex. 2). The Request explicitly notified Smith that: (1) A matter is admitted unless, within 30 days after being served, the party to whom the request is directed serves on the requesting party a written answer or objection addressed to the matter and signed by the party or its attorney. A shorter or longer time for responding may be stipulated to under Rule 29 or be ordered by the court; and (2) A matter admitted under Rule 36 of the Federal Rules of Civil Procedure is conclusively established unless the court, on motion, permits the admission to be withdrawn or

amended (*Id.*). Smith has failed to respond to the Request (and his time for doing so has expired) and Smith has chosen not to participate in this litigation since the filing of his “answer.”

## **ARGUMENT AND AUTHORITIES**

### **I. SMITH VIOLATED THE ANTI-KICKBACK STATUTE**

To establish a violation of the AKS, the United States must show that: (1) the defendant offered or paid remuneration; (2) one purpose of the remuneration was to induce the recipient to prescribe or recommend goods or services for patients, including federal health care program beneficiaries; and (3) the defendant acted knowingly and willfully. 42 U.S.C. § 1320a-7b(b).

Courts have broadly defined “remuneration,” interpreting it to mean “anything of value.” *U.S. v. Chang*, 2017 WL 10544289, at \*7 (C.D. Cal. July 25, 2017) (listing authorities). “Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.” 42 CFR § 1001; 56 Fed.Reg. 35,952, 35,957 (1991). The AKS prohibition applies to “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. §§ 1320a-7b(b)(1), (2).

In the context of the AKS, “induce” means to intend to exercise influence over the reason or judgment of another in an effort to cause the referral of goods or services, and the AKS prohibits any arrangement where *at least one* purpose of the remuneration is to induce referrals. *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014); *see also U.S. v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (“If the payments were intended to induce the physician to use Cardio-Med’s services, the statute was violated, even if the payments were also intended to compensate for professional services.”); *U.S. v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (rejecting the “primary

motivation” theory); *U.S. v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) (same); *U.S. v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (same); *U.S. v. Kats*, 871 F.2d 105, 108 (9th Cir.1989) (same).

“Knowingly” and “willfully” mean that a party has acted with a purpose to commit a wrongful act. *U.S. v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 510 (D.S.C. 2016) (citing *McClatchey*, 217 F.3d at 829). The United States does not need to prove that the defendant that knew the arrangement for referrals violated the statute, but only knowledge that the conduct was unlawful, *i.e.*, ignorance of the law is no excuse. *U.S. v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (“Indeed, the giving or taking of kickbacks for medical referrals is hardly the sort of activity that a person might expect to be legal.”). The Government need not prove that a defendant had a specific intent to violate the AKS. *See* 42 U.S.C. § 1320a-7b(h).

***1. Smith pays Lord’s medical management company \$300,000***

There is no question that Smith & Sons Ent, LLC’s payments of \$50,000 and \$250,000 to Optimed in August and September of 2012, respectively, constitute remuneration under the AKS. When Smith paid this remuneration, he did so with at least one purpose of inducing the referral of UDTs for patients, including Medicare beneficiaries, from APT.

When Sonia Foster took over APT, its referral of patient samples to PCLS for UDT decreased (Ex. 2 at ¶6). In fact, from mid-June 2012 through August 31, 2012, APT referred no patient samples to PCLS for urine drug testing (J.L. 82:8-17; Ex. 2 at ¶7). Smith was concerned about the decrease or cessation in referrals from APT and the resultant lack of revenue generated by PCLS as a result of APT’s declining business (Ex. 2 at ¶8).

Smith and Lord discussed Optimed’s purchase of APT—priced over \$800,000—on one occasion, for approximately 30 minutes (J.L. 58:8-14). Smith paid Lord \$300,000 without any written agreements, terms, conditions or expectation of repayment (J.L. 57:15-58:6, 58:22-24).

Lord recruited one of his own employees, Portia Hutchinson, to act as a straw purchaser and owner of APT, while he took steps to ensure that she would never be financially liable for the practice (J.L. 34:10-14). When the sale was consummated, Lord took control of its business and operations; for example, he renamed it, caused it to enter into a management contract with Optimed, hired a medical director and later a management director, and took over the practice's finances, personnel, IT and other issues (J.L. 30:16-17, 35:10-20, 49:1-10, 49:17-15); Ex. 2 at ¶¶ 23, 24). Finally, Lord initially testified that he understood that when the purchase of APT was finalized, APT would have to use PCLS for confirmation testing (J.L. 26:21-27:12). Lord later claimed the use of PCLS was not discussed (J.L. 58:8-21).<sup>3</sup> But while Lord testified that he was not involved in medical decision-making at the practice (J.L. 75:7-13), after Lord took over the practice, it began referring to PCLS again (J.L. 77:25-78:21, 82:5-17). These facts, about which there is no genuine dispute, show that Smith paid \$300,000 to Lord to finance the purchase of APT in order to induce referrals of UDTs to PCLS and thereby violated the AKS.

Smith is not insulated from liability merely by virtue of the fact that Lord was not the physician sending in the samples, as the AKS also prohibits payments to laypersons who have the ability to influence or direct referrals. *See U.S. v. Vernon*, 723 F.3d 1234, 1254 (11th Cir. 2013) (“[Defendant] argues that because [the kickback recipient] is not a physician, she could not ‘refer’ patients to Medfusion within the meaning of subsection (b)(2)(A) of § 1320a–7b. This argument wholly fails because the plain language of the statute is not limited to payments to physicians who prescribe medication. Rather, it speaks broadly to ‘whoever knowingly and willfully . . . pays any

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<sup>3</sup> Note that the AKS also provides for criminal penalties for those who solicit or accept bribes or kickbacks in exchange for referrals. 42 U.S.C. § 1320a–7b(b)(1).

remuneration’ to ‘*any person* to induce such person . . . to refer an individual’ to Medfusion for an item or service paid by Medicaid.”) (emphasis in original).

The Seventh Circuit’s decision in *United States v. Polin*, 194 F.3d 863 (7th Cir. 1999), is particularly instructive here. There, the court affirmed AKS convictions of two defendants who were employees of a pacemaker monitoring service that made payments—based on the number of patients referred to the defendants’ employer—to an independent sales representative for the services. *Id.* at 864-65, 867. The evidence showed that the sales representative was responsible for selecting an outside monitoring service such as defendants’ company once a physician determined that such services were necessary and that although “the physician had the right to refuse any [monitoring] service he chose, . . . [the sales representative] had never been overruled by a physician during his fourteen year career.” *Id.* at 865. Ultimately, the Seventh Circuit concluded that it was a “classic case of an illegal kickback prohibited by 42 U.S.C. § 1320a–7b(b)(2)(A). In exchange for directing Medicare patients to [the defendant company], [defendants] were willing, and did, pay [the sales representatives] money.” *Id.* at 867.

The same classic kickback case is found here: Smith paid Lord \$300,000, which he knew Lord would use to purchase a medical practice, in exchange for Lord directing the UDTs of that practice’s patients, including Medicare beneficiaries, to PCLS through his position and influence as the practice manager. *See also U.S. v. Shoemaker*, 746 F.3d 614, 629 (5th Cir. 2014) (“Moreover, sufficient evidence established that the payments to Chandler aimed to induce him to ‘recommend’ Garner's company. 42 U.S.C. § 1320a–7b(b)(2)(B). That is, in paying Chandler, Garner was not asking for a brochure bearing his company’s name to be distributed to TLMC staff; rather, *enough evidence showed that he wanted Chandler to exploit his personal access to TLMC executives, including Shoemaker, and to ensure that TLMC favored Garner’s company when it*

*chose nursing services. This conduct is an archetypal example of the undue influence prohibited by the statute.”*) (emphasis added).

Ultimately, the United States contends that Lord controlled SSPA, in all respects, including directing providers to send samples for UDTs to PCLS. The only reasonable conclusion that can be drawn from the fact that Smith paid Lord’s company \$300,000 to assist Lord in purchasing a pain clinic is that he was doing so to induce the referral of samples to PCLS.

**2. *Smith knowingly and willfully violated the AKS.***

As an initial matter, Smith was well aware of the AKS and its implications for health care providers that bill Medicare—because at one time, he was a licensed medical provider.<sup>4</sup> Second, he paid for Lord’s acquisition of APT, a known PCLS referral source, and there is a lack of evidence that Smith availed himself of the counsel of his co-owners, colleagues, or the compliance team at PCLS, before doing so.<sup>5</sup> PCLS had a compliance department and written policies or procedures related to the AKS, and it put on compliance and regulatory training for its sales force, owners, and Board of Directors, including trainings on the AKS (M.S. 20:13-25; Ex. 10: Deposition of Alan Campbell (“A.C.”) 26:4-27:9). Smith was, by virtue of his ownership and membership on the Board, aware of and had access to PCLS’ compliance department, and could have obtained guidance and counsel as to these payments, but he chose not to (thereby concealing his conduct from PCLS). *See U.S. v. Lusk*, 2017 WL 508589 (S.D. W.Va. Feb. 7, 2017) (concealment of fraud probative of wrongful intent).

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<sup>4</sup> Smith was a licensed medical doctor in the State of Florida until he lost his license (Ex. 9: Deposition of Marcus Sowinski (“M.S.”) 76:1-14).

<sup>5</sup> Wiegel was aware Smith had multiple business ventures with Lord, generally, and testified that he was nervous Smith and Lord were acting outside PCLS’ “compliance net” (J.W. 57:13-58:7). Sowinski testified that he learned about Lord’s acquisition of APT either while it was in process or after the fact, but did not know if Smith was involved (M.S. 78:18-25, 80:24-81:5).

Finally, “evidence of financial gain is particularly probative in a [health care] fraud case to establish the defendant’s intent to defraud.” *U.S. v. Bajoghli*, 785 F.3d 957, 966-67 (4th Cir. 2015) (citing *U.S. v. Beverly*, 284 F. App’x 36, 40 (4th Cir. 2008); accord *U.S. v. Davis*, 490 F.3d 541, 549 (6th Cir. 2007); see also *U.S. v. Dearing*, 504 F.3d 897, 901 (9th Cir. 2007) (discussing evidence from which a fact-finder could infer willful intent to defraud); *U.S. v. Wheeler*, 889 F. Supp. 2d 64, 68 (D.D.C. 2012) (reiterating Davis holding in context of § 1347 health care fraud prosecution). From approximately 2011 through 2013, PCLS had close to \$100 million in profit and tax distributions among the four owners (A.C. 41:21-42:14). From 2010 through 2014, Smith received at least \$47 million in distributions from PCLS.<sup>6</sup>

## **II. SMITH’S AKS VIOLATIONS GIVE RISE TO FCA LIABILITY**

The United States is entitled to summary judgment under the FCA because, as a matter of law, Smith’s violations of the AKS also constitute violations of the FCA. Four elements must be established to prevail under the FCA: (1) Defendant submitted or caused to be submitted claims for payment to the federal Government; (2) the claims were false or fraudulent; (3) Defendant acted knowingly; and (4) the falsity or fraud was material to the Government’s payment decision. 31 U.S.C. 3729(a)(1)(A); *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015) (vacated and remanded on other grounds).

As to the first element, Smith caused claims tainted by the kickback payments to Lord and Optimed to be submitted for payment to the federal government. It is undisputed that PCLS submitted claims for reimbursement<sup>7</sup> to the Medicare Program for UDTs performed on beneficiary

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<sup>6</sup> This is reflected on his Alabama Department of Revenue Schedule K-1 for tax years 2011-2014. Copies are available upon request.

<sup>7</sup> A “claim” is statutorily defined as a “request or demand, whether under a contract or otherwise, for money or property.” 31 U.S.C. § 3729(b)(2).

samples. That PCLS as a company was the one to actually submit the claims does not insulate Smith. Rather, “[t]he FCA places liability not only on persons who cause false claims to be submitted . . . but also on those who cause the claims . . . to be false in the first place.” *Mason v. Medline Indus., Inc.*, 731 F.Supp.2d 730, 738 (N.D. Ill. 2010) (further noting “[t]he wealth of case law supports the proposition that the FCA reaches claims that are rendered false by one party, but submitted to the government by another”) (collecting authorities); *see also U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 390 (1st Cir. 2011) (“We have made clear that unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party.”).

As to the second element, “[a]n AKS violation resulting in a federal health care payment automatically constitutes a false claim under FCA.” *U.S. ex rel. Hartnett v. Physicians Choice Laboratory Services, LLC*, 2020 WL 571322, at \*3 (W.D.N.C. Feb. 5, 2020) (Bell, J.) (citations omitted); *see also U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498 (D.S.C. 2016) (collecting cases). Likewise, the fourth element is met as a matter of law. *See Berkeley Heartlab, Inc.*, 2017 WL 6015574 (D.S.C. Dec. 4, 2017) (“AKS violations are *per se* material.”); *U.S. ex rel. Goodman v. Arriva Medical, LLC*, 2020 WL 3840446 (M.D. Tenn. July 8, 2020) (discussing materiality post-*Escobar* and in the AKS context).

As to the third element, “[s]cienter under the FCA encompasses actual knowledge, deliberate indifference, and reckless disregard, but does not require proof of specific intent to defraud.” *Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015) (vacated and remanded on other grounds) (*citing* 31 U.S.C. § 3729(b)(1)). It is well-established that if a party has the requisite intent to induce and, as a result, violate the AKS, and causes the submission of claims for payment

to Medicare, then that person also violates the FCA. *See U.S. ex rel. McNutt v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259 (11th Cir. 2005).

The evidence supporting the FCA's scienter element is the same as that discussed to support the Government's contention that Smith acted knowingly and willfully, in violation of the AKS. Alternately, this evidence demonstrates that Smith acted with reckless disregard, by failing to make reasonable efforts to ensure that his "financial arrangement" with Lord and Optimed complied with the AKS *before* PCLS filed claims with Medicare for reimbursement for tests ordered by SSPA practitioners. *See Heckler v. Cmt. Health Srvs. of Crawford*, 467 U.S. 51, 64 (1984) ("As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements.").

### **III. DAMAGES**

The False Claims Act mandates the assessment of treble damages plus a per-claim penalty. *See U.S. v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (citing 31 U.S.C. § 3729(a)); *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 675 F.3d 394, 397 (4th Cir. 2012). The United States' single damages consist of the claims submitted to Medicare that are tainted by a kickback, and thus false in their entirety. *See United States v. Rogan*, 459 F. Supp. 2d 692, 726-27 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008) (finding that United States' damages are the value of the claims submitted tainted by kickbacks and were established by "competent evidence introduced by the Government, including the business records of CMS that reasonably fixed those amounts paid by the Government for services"). Here, the United States' retained expert, Eric Hanes, has analyzed the claims data and has identified 5,172 claims submitted by PCLS for UDTs referred by SSPA providers during the taint period of August 1, 2012 through July 31, 2014 (Ex. 11: Rule 26(b) Expert Report of Eric Hines, CPA, CFF, CHC at ¶¶ 14, 29-32). Hines has further

determined that Medicare paid PCLS \$2,655,666 in reimbursement for these tainted claims, which is representative of the single damages to the United States (*Id.* at ¶14).

The United States is also entitled to civil penalties in the range of \$5,500 to \$11,000, which are calculated on a per-claim basis. *See* 31 U.S.C. § 3729(a); *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 675 F.3d 394, 397 (4th Cir. 2012); *see also Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001) (“Each submission of the [CMS] – 1500 form ... qualifies as a claim made to the United States” for purposes of calculating penalties); *Krizek*, 111 F.3d at 940 (accord). The United States respectfully requests that, upon a finding of liability, the Court treble any single damages found and impose penalties per claim in the statutory range as appropriate.

### **CONCLUSION**

The Court should grant the United States’ Motion for Partial Summary Judgment.

Respectfully submitted this 8th day of December, 2020.

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**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing document will be served on the 9th day of December, 2020, by depositing a copy, correctly addressed and postage prepaid, with the United States Postal Service, on the below party:

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